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Exporter Guide

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Report Highlights:

Executive Summary: This report provides an overview of additional documentation and information that may be requested of U.S. exporters and suppliers when exporting food and agricultural products that are regulated by Mexico's Ministry of Health (SALUD).

General Information:

Author Defined:

DISCLAIMER: This report was prepared by the Agricultural Trade Office of the USDA Foreign Agricultural Service in Monterrey, Mexico, for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are

normally best equipped to research such matters with local authorities, before any goods are shipped. Final import approval of any product is subject to the importing country's rules and regulations as interpreted by border officials at the time of product entry.

EXPORT DOCUMENTATION REQUESTED BY MINISTRY OF HEALTH

Several Mexican government agencies are involved in the import clearance process for food and agricultural products, including the Ministry of Finance, through the Customs' General Administration, and the Ministry of Agriculture, through the National Animal & Plant Health, Food Safety and Quality Inspection Service. In some cases, however, the Ministry of Health ([SALUD](#)), through the Federal Commission for the Protection against Sanitary Risks ([COFEPRIS](#)), is also involved in the import clearance process. COFEPRIS is the in charge of the control and surveillance of food and beverages, food supplements, tobacco, plant nutrients, toxic or dangerous substances, biotechnology products and pesticides among others.

Although the Mexican importer, via a custom broker, is responsible for submitting all needed documentation to Mexican authorities, U.S. exporters may be asked to provide information to comply with Mexican import regulations. Such information may include labels, certificates of origin, and microbiological analysis. Understanding such documentation requirements will result in smoother clearance and will help to avoid costly delays and rejections.

On September 27, 2007, in coordination with the Ministry for the Economy ([SE](#)), SALUD published the “Agreement that Establishes the Classification of Products whose Import or Export is Subject to Sanitary Regulations from the Ministry of Health” [1] . This agreement lists the tariff codes of products subject to SALUD regulation and specifies which products require either a Sanitary Import Permit or a Sanitary Import Notification, which must be included in the import documentation submitted by the customs broker. A list of the tariff codes for imported products under this regulation can be found in GAIN report [MX9501: “Mexico Imported Products Regulated by the Ministry of Health \(SALUD\)”](#).

1. THE SANITARY IMPORT PERMIT

When importing products that will be used for human consumption and that are listed in the aforementioned agreement, Mexican importers must request an “Advance Sanitary Import Permit for Products” (Spanish: *Permiso Sanitario Previo de Importación de Productos*) from COFEPRIS.

This permit can only be requested by the Mexican importer/buyer, but includes documentation that might be requested from U.S. exporters and suppliers depending on the product and procedure chosen to request the Permit.

This permit can be requested under two different procedures:

1. Procedure COFEPRIS 01-002-A: Sanitary Import Permit for Products using a Health Certificate

When using this procedure, the importer must fill out the Permit request form and attach the following documentation:

- a. Original Health Certificate or Health Declaration (Spanish: *Constancia Sanitaria*)
- b. Specific analysis (see definition in Section 3.6, below), if applicable
- c. Original label used in country of origin
- d. Spanish-language label to be used in Mexico

2. Procedure COFEPRIS 01-002-B: Sanitary Import Permit for Products using Free Sale Certificate

In this case, the importer must submit the Permit request and include the following documents:

- a. Original Free Sale Certificate
- b. Physicochemical, microbiological analysis; must include Specific analysis when applicable
- c. Original label used in country of origin
- d. Spanish-language label to be used in Mexico

2. THE SANITARY IMPORT NOTIFICATION

SALUD has defined a list of products that, when imported and intended for human consumption, require the Mexican importer to request a “Sanitary Import Notification” (Spanish: *Aviso Sanitario de Importación*) from COFEPRIS (please see GAIN report [MX5901](#) for the list of products that need to comply with this requirement).

Once again, the notification can only be requested by the Mexican importer/buyer, and may include documentation that the U.S. exporter or supplier may be requested to provide.

1. Procedure COFEPRIS 01-006 – Sanitary Import Notification

When using this procedure, the importer must fill out a permit request and attach the following documentation:

- a. Original Health Declaration (Spanish: *Constancia Sanitaria*) or Free Sale Certificate

3. DEFINITIONS OF REQUIRED DOCUMENTATION

Following is a list of documentation and information that exporters/suppliers may be requested to provide during the import process. Definitions and explanations of this information are outlined in SALUD’s “Agreement which specifies the Characteristics that must be met by the Documentation Required when Requesting a Sanitary Import Permit or a Sanitary Import Notification” [2]. The following are specified in Article 2 of this agreement as follows:

1. Health Certificate: Document issued by the country of origin’s health authority, valid for one year, which declares that the product complies with sanitary regulations.
2. Health Declaration: Document issued by the country of origin’s health authority, responsible for regulating the process and quality of the product or input to be imported, where evidence is provided to guarantee that the product is safe for human use/consumption, indicating its physicochemical composition and including microbiological and specific analysis, when applicable. The Declaration should also state the geographical origin of the product, and the validity of such analysis should be specified by lot number.
3. Free Sale Certificate: for sanitary purposes, a document submitted by the foreign health authority responsible for ensuring that products and inputs comply with legal requirements and can be used or consumed freely, with no restrictions, in the country of origin. Such certificate should be valid for one year.
4. Physicochemical analysis: Determination of the representative values of the product or input to be imported, carried out in the country of origin by the producer or a domestic or foreign laboratory accredited by the related government agency or office, printed on official paper, with the name, signature and position of the responsible agent [3]. The validity of such analysis should be specified by lot number.
5. Microbiological analysis: Determination of pathogen and non-pathogen microorganisms, carried out in the country of origin by the related government agency or office, printed on official stationery, with the name, signature and position of the responsible agent. The validity of such analysis should be specified by lot [4].
6. Specific analysis: Carried out in the country of origin by the producer or a domestic or foreign laboratory accredited by the related government agency, printed in official paper. Specific analyses are requested when products originate from highly polluted regions, radioactive contaminated areas or regions affected by particular diseases such as cholera. Currently, no specific analyses are required for products from the United States.

4. HEALTH CERTIFICATES, DECLARATIONS AND FREE SALE CERTIFICATES

Unfortunately, there are no specific guidelines for the phrasing and suggested structure of these documents. Mexican importers rely on trial and error when submitting information to COFEPRIS. It is worth mentioning that if COFEPRIS determines that the information/documentation submitted is not correct, the applicant has 5 working days to correct the information or documents. After five days, the importer must re-start the request process.

5. SANITARY SPECIFICATIONS OF SALUD-REGULATED PRODUCTS

SALUD has issued several standards (*Norma Oficial Mexicana, NOM*), which detail the specific sanitary requirements that products under its jurisdiction must comply with in order to be allowed to be distributed for human consumption. In these NOMs, specific details are provided on the physicochemical and microbiological characteristics that such products should meet, thus setting the limits and tolerances that required documentation must report when requesting the Sanitary Import Permit. The complete list of NOMs available can be searched at: <http://www.economia-noms.gob.mx/> (only Spanish versions are available)

6. PHYSICOCHEMICAL & MICROBIOLOGICAL ANALYSIS GUIDELINES

Mexico also has several NOMs that explain and detail how physicochemical, microbiological and specific analysis should be carried out. These are:

[NOM-092-SSA1-1994](#) – Methodology for counting aerobic bacteria

[NOM-110-SSA1-1994](#) – Food sampling and preparation of dilutions for microbiological examination

[NOM-111-SSA1-1994](#) – Determination and enumeration of yeast and molds in food

[NOM-112-SSA1-1994](#) – Enumeration of coliforms: Most probable number technique

[NOM-113-SSA1-1994](#) – Enumeration of coliforms: Colony count technique

[NOM-114-SSA1-1994](#) – Detection method for *Salmonella* in food [5]

[NOM-115-SSA1-1994](#) – Detection method for *Staphylococcus aureus* in food

[NOM-117-SSA1-1994](#) – Detection of cadmium, arsenic, lead, tin, copper, iron, zinc and mercury in food, tap and purified water: atomic absorption spectrophotometric method

[NOM-143-SSA1-1995](#) – Detection of *Listeria monocytogenes* in food [6]

7. POST CONTACTS AND FURTHER INFORMATION

Agricultural Trade Offices of the USDA's Foreign Agricultural Service in Mexico offer a wide range of marketing programs and services to help U.S. suppliers understand the Mexican market and promote their products to potential clients. Likewise, these offices offer services and activities to assist buyers in Mexico when locating and sourcing U.S. food and agricultural products.

If you have any questions or comments regarding this report or need assistance exporting food products to Mexico, please contact us at the following addresses:

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Relevant Reports Submitted by FAS/Mexico:

[MX8314 Mexico FAIRS Report](#)

[MX8503 Mexico Export Certificate FAIRS Report](#)

[MX9501 Mexico Imported Products Regulated by the Ministry of Health \(SALUD\)](#)

^[1] Spanish: *Acuerdo que establece la clasificación y codificación de mercancías y productos cuya importación, exportación, internación o salida está sujeta a regulación sanitaria por parte de la Secretaría de Salud*, full text available at: <http://www.siiex.gob.mx/portalSiiex/Mes/2007/SEPTIEMBRE/27092007/sanitaria.doc>

^[2] Spanish: *Acuerdo por el que se especifican las características de los documentos anexos para realizar los trámites de solicitud de permiso sanitario previo de importación de productos y de aviso sanitario de importación de productos*, full text available at: <http://www.salud.gob.mx/unidades/cdi/nom/compi/ac201206.pdf>

^[3] Responsible agent could be a lab supervisor, quality control manager, chemical engineer or any related position.

^[4] Most of the times, the microbiological analysis information is described in the products' related Mexican Official Norm (NOM); see Section 5 of this report.

^[5] Addendum and corrections can be found at: <http://www.economia.gob.mx/work/normas/noms/kferar/a114ssa1.pdf>

^[6] Addendum and corrections can be found at: <http://www.economia.gob.mx/work/normas/noms/kferar/a143ssa1.pdf>